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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,608	04/28/2006	Jan Faergemann	G8575.0002	6148

32172 7590 12/01/2010

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EXAMINER	
RAMACHANDRAN, UMAMAHESWARI	
ART UNIT	PAPER NUMBER
1627	
MAIL DATE	DELIVERY MODE
12/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,608	FAERGEMANN ET AL.	
	Examiner	Art Unit	
	UMAMAHESWARI RAMACHANDRAN	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 September 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,8-14 and 18-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2, 4, 8-14, 18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner notes the receipt of the amendments and remarks received in the office on 9/29/2010 amending claims 1 and 18 and adding new claims 26 and 27. Claims 3, 5-7, 15-17 have been cancelled. Claims 1-2, 4, 8-14, 18-27 are pending and are being examined on the merits herein.

Response to Remarks

Applicants' have stated that "Since the obviousness-type double patenting rejection is provisional, no response is required at this time" and have not put forth any arguments with respect to the ODP rejection. Hence the rejection is maintained and is given below for Applicants' convenience. Applicants' amendment of claims necessitated the modified 112(1) rejection and 103(a) rejections presented below. Applicants' arguments regarding the 112(1) and 103(a) rejections has been fully considered and found not to be persuasive. The arguments are addressed in response to arguments section below. Accordingly, the action is made final.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577.

Claims 1 and 18 of the instant application is drawn to a method of inhibiting the growth of bacteria or a method of disinfecting a non-porous surface contaminated with multiple resistant bacteria wherein the multiple-resistant bacteria is at least one member of the group consisting of Staphylococcus aureus resistant to methicillin or fucidic acid, coagulation- negative staphylococci, Enterococcus resistant to fucidic acid, vancomycin, ciprofloxacin or trimetoprim, enterobacteriaceae with plasmid-encoded extended-spectrum beta-lactamases, Acinetobacter resistant to cefadroxil, nitrofurantin or mecillinam, antibiotic-resistant Serratia maltophilia, Pseudomonas aeruginosa resistant to vancomycin, ciprofloxacin or trimetoprim, and trimetoprin resistant E.coli comprising administering a disinfecting composition comprising 15% or more by weight of pentane 1,5 diol.

Claims 1, 2, 4, 7, 8, 10, 11, 20, 22, 23, 24, 26 of copending Application No. 11/791,577 are drawn to a pharmaceutical composition comprising 15, 16, 17, 18, 19 or 20 % weight of the diols including 1, 5 pentane diol and use of such composition as antimicrobial composition.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the co-pending application teach the use of a pharmaceutical composition comprising 1, 5 pentane diol in treating microbial infections.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 4, 8-14, 18-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for determining minimum inhibitory concentration for different strains of s.aureus, Staph, MRSA, enterococcus, E.coli, Enterobacter and resistance indicated against selected antibiotics (methicillin resistant, fucidic acid resistant, coagulation-negative Staph with respect to fucidic acid, vancomycin resistant enterococci etc but does not reasonably provide enablement for inhibiting the growth of enterobacteriaceae with plasmid-encoded extended- spectrum beta lactamases and antibiotic-resistant Serratia maltophilia or coagulation-negative Staph with respect to antibiotics other than fucidic acid as claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and, (8) the quantity of experimentation necessary.

(1, 5) The nature of the invention and the Breadth of the Claims:

The instant claims are drawn to a method of inhibiting the growth of multiple resistant bacteria wherein the multiple-resistant bacteria is at least one member of the group consisting of Staphylococcus aureus resistant to methicillin or fucidic acid, coagulation- negative staphylococci, Enterococcus resistant to fucidic acid, vancomycin, ciprofloxacin or trimetoprim, enterobacteriaceae with plasmid-encoded extended-spectrum beta-lactamases, Acinetobacter resistant to cefadroxil, nitrofurantin or mecillinam, antibiotic-resistant Serratia maltophilia, Pseudomonas aeruginosa resistant to vancomycin, ciprofloxacin or trimetoprim, and trimetoprin resistant E. coli comprising administering 15% by weight or more of pentane 1,5 diol as multiple resistant bacteriostatic agent. The claims are limited to the multiple resistant bacteria claimed. However the claim is broad with respect to the strains of enterobacteriaceae with plasmid-encoded extended- spectrum beta-lactamases, antibiotic-resistant Serratia

maltophilia or coagulation-negative Staph with respect to antibiotics other than fucidic acid.

(*2)/(3) The state of the art /The predictability of the art:*

The article 'Beta-lactamases' (http://en.wikipedia.org/wiki/Beta-lactamase) teaches that beta-lactamases are enzymes produced by some bacteria and are responsible for their resistance to beta-lactam antibiotics like penicillins, cephamycins, and carbapenems (ertapenem). Cephalosporins are relatively resistant to beta-lactamase. In summary, the bacteria encoded by beta lactamases are resistant to several antibiotics including penicillins, cephamycins, carbapenems, cephalosporins etc. Kataoka et al. (Intl J of Antimicrobial Agents 22, 2003, 601-606) teaches *Stenotrophomonas maltophilia* is found in a wide variety of environments and has a marked resistance to extended-spectrum cephalosporins, carbapenems and aminoglycosides (see introduction). It is known in the art that coagulation-negative Staph is resistant to linezolid, oxacillin, teicoplanin, ciprofloxacin etc. The document 'http://www.dhh.louisiana.gov/offices/miscdocs/docs-249/vet/ulti%20drug %20resistance/09/StaphCN08.pdf' teaches that coagulation-negative Staph is resistant to multiple antimicrobials. Despite the advanced studies in antibiotic resistance of bacteria it is still not predictable from the art or from the specification that 1, 5 pentane diol can inhibit the growth of all strains of enterobacteriaceae with plasmid-encoded extended- spectrum beta-lactamases, antibiotic-resistant Serratia maltophilia or coagulation-negative Staph with respect to antibiotics other than fucidic acid. Applicants

have claimed several types and strains of bacteria that are resistant to drugs not tested by the Applicants.

(4) The relative skill of those in the art:

The relative skill of those in the pharmaceutical development and medical treatment arts is high, requiring advanced education and training.

(6, 7) The amount of guidance given and the presence of working examples:

It has been established that, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." *In re Fisher*, 427 F.2d 833, 839 166 USPQ 18, 24 (CCPA 1970). The specification provides guidance to determining minimum inhibitory concentration (MIC) for different strains of s.aureus, Staph, MRSA, enterococcus, E.coli, Enterobacter and resistance indicated against selected antibiotics methicillin resistant, fucidic acid resistant, coagulation-negative Staph (fucidic acid), vancomycin resistant enterococci etc for the drugs fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim (see p 6-8 of the specification)

(8) The quantity of experimentation necessary:

Given that the instant claims encompass administration of 15% of pentane 1,5 diol as multiple resistant bacteria bacteriostatic agent, the guidance of the specification is towards determining the MIC and growth inhibition for multiple resistant bacteria where the drugs are fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim. One having ordinary skill in the art have to conduct

experiments to find out whether pentane 1,5 diol is multiple resistant bacterial bacteriostatic agent for different multiple drug resistant bacteria such as enterobacteriaceae with plasmid-encoded extended- spectrum beta-lactamases, antibiotic-resistant Serratia maltophilia or coagulation-negative Staph with respect to antibiotics other than fucidic acid and for their various strains for the drugs that they are resistant to. First a person of ordinary skill in the art have to conduct experiments (for yet to be discovered, multiple resistant bacteria) or research from prior art to find out the type of drug(s) the bacterial strain is resistant to and then conduct experiments with 1, 5 pentane diol to find out at whether the compound inhibits the growth of that particular strain and its minimum inhibitory concentration. There is no guidance provided in the specification to conduct experiments to test the drug(s) to which bacterial strain they are resistant to. In order to practice the above claimed invention, one of ordinary skill in the art would have to first determine the drug(s) that are proven to be resistant to and predict which different bacterial strains would be resistant to the different drugs and the concentration of 1, 5 pentane diol for inhibiting the growth of such multiple resistant bacteria. Therefore, it would require undue, unpredictable experimentation to find whether pentane 1,5 diol is a multiple-resistant bacteriostatic agent, that is an agent that inhibits the growth of all multiple resistant bacteria that is known and yet to be discovered. Genetech, 108 F.3d at 1366 states that “a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion” and “patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 8-10, 18, 22, 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck et al. (U.S. 5,369,129).

Swanbeck et al. teaches a preparation for topical treatment of infections caused by virus, fungi, bacteria comprising 1, 5 pentane diol. The reference teaches a composition comprising 50% of 1, 5 pentane diol and 50% ethanol solution (see abstract, col1, lines 56-57). Also, the reference has data showing a study of pentane-1,5 diol against certain bacteria such as S.aureus, S.epidermidis, C.albicans, T.rubrum, P.avale (Table 1). The reference teaches a method of treating an infection caused by a virus by topical administration of a composition comprising 1,5-pentane diol.

The reference does not explicitly teach the topical administration of the composition in patients with bacterial infections.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have topical administered a composition comprising 15% by weight or more of pentane 1,5 diol and a pharmaceutical carrier in a method of treating patients with bacterial infections because the patent title is "Preparation of topical treatment of infections caused by bacteria" and the patent teaches administration of such composition to patients with herpes virus. The reference teaches the preparation of the composition claimed and administration of the same to the patients with viral infections. Also, the reference teaches that formulation is effective against bacteria such as S.aureus, S.epidermidis, C.albicans, T.rubrum, P.avale (Table 1). One having ordinary skill in the art would have been motivated to administer the composition claimed to patients with bacterial infections topically in expectation of success as well to achieve the therapeutic benefits attained in such administration. The reference shows data in study 2 of the activity of pentane 1, 5 diol against various bacteria and an in vitro study of using pentane 1, 5 diol to study its activity against virus. Though the reference does not explicitly teach addition of an antimicrobial composition comprising pentane 1, 5 diol to non-porous surface in a method of disinfecting however it is obvious to one having ordinary skill in the art that addition of such composition to glass surfaces indicates a method of disinfecting the glass surface or non porous surface as pentane 1, 5 diol is taught as an antibacterial agent by Swanbeck. The reference does not explicitly teach rinsing the surface with water or an aqueous detergent composition after treating the surface with 1, 5 pentane diol. It would have been obvious to one having ordinary skill in the art at the time of the invention to have rinsed surfaces at least with water that has

been treated with disinfectants or antimicrobial such as 1, 5 pentane diol in order to clean and remove the antimicrobial composition from the surface.

Claims 1, 8, 10-13, 20, 22, 23, 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. 6,348,203) and further in view of Tsao et al. (U.S. 5,411,597).

Goodman et al. teaches a method of preparing a viscous hydrogel composition, for use in a topical treatment of a skin condition including a pharmaceutically active agent, a polysaccharide, gelling or a thickening agent (col.2 , lines 12-13) (e.g. hydroxy alkyl cellulose), a water-miscible organic solvent and water, wherein the pharmaceutically active agent is an antimicrobially active nitroimidazole drug (0.75% in example 1), the water-miscible organic solvent is a water-miscible alkylene glycol that includes pentylene glycol (synonym of 1,5 pentylene glycol or 1, 5 pentane diol) (see abstract, col. 5-6, claim 1, claims 22, 17, 18, 19). Also, the reference teaches that the composition is useful in treating conditions involving infection responsive to an antimicrobially active nitroimidazole drug.

The reference teaches up to 5% of alkylene glycol in example 1 but does not explicitly teaches the composition comprises 15% by weight of more of pentane 1-5 diol

Tsao et al. teaches a disinfection solution comprising C2-C6 alkanol, C3-C8 alkylene glycol, a pharmaceutically acceptable surfactant, optionally a buffer and water (see Abstract). The reference further teaches that the alkylene glycol is selected from 1,2-propylene glycol, 1,2-butylene glycol, 1,5-pentylene glycol etc and the amount range from 10-50% by weight (col. 3, lines 13-19, lines 20-25). The reference also teaches

addition of a surfactants and viscosity enhancers such as hydroxy methyl cellulose (col. 7, lines 40-50) to the composition.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Goodman's composition to add more 1, 5 pentane diol to formulate a composition comprising 15% by weight of more of pentane 1-5 diol because of the teachings of Tsao et al. Tsao et al. teaches disinfectant solution primarily for use in contact lenses comprising alkylene glycols such as pentylene glycol in an amount ranging from 10-50% by weight. One having ordinary skill in the art would have been motivated to add such an amount of pentane 1, 5 diol to Goodman's composition in expectation of success in preparing such formulations and using the same in treating infections.

Claim 13, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al. (U.S. 6,348,203) and further in view of Tsao et al. (5,411,597) as applied to claims 1, 8, 10-13, 20, 22, 23, 24 above and further in view of Noll et al. (U.S. 5,370,876).

Goodman et al. and Tsao et al. teachings discussed as above. Tsao teaches addition of surfactants to the composition comprising alkylene glycols. The reference does not teach explicitly the addition of a detergent in the composition.

Noll et al. teaches a protective skin cream composition comprising 15-40 wt % of an alkali metal fatty acid salt, an effective amount of an antimicrobial compound, 5-20% of a polyol effective as an emollient (See abstract). The reference further teaches that the water soluble salts of fatty acids are used to provide water repellency.

It would have been obvious to one having ordinary skill in the art to have added detergents such as salts of a fatty acid in the antimicrobial composition of Goodman et al. because of the teachings of Noll. Noll teaches antimicrobial compositions comprising antimicrobial agents, alkali metal fatty acid salt, polyols etc for use as protective creams for healthcare workers. Polyols include pentylene glycol according to the prior art teachings of Tsuzuki et al. (see claim 5, U.S. 6,121,327). One having ordinary skill in the art would have been motivated in adding such salts in an antimicrobial composition comprising an antimicrobial agent and a polyol in expectation of success in preparing such formulations and using the same for therapeutic purposes and also to provide water repellency.

Claims 4, 14, 19, 21, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanbeck et al. (U.S. 5,369, 29) as applied to claims 1, 2, 8-10, 18, 22 and in view of Buseman et al. (U.S. 2002/0192273).

Swanbeck et al. teachings discussed as above.

The reference does not teach the carrier comprises a patch of a woven or non-woven material or combination thereof.

Buseman et al. teaches adhesive patches for treating or preventing bacterial infections for topical applications in a mammal (see p 22-23, claims 100-103). The reference teaches the adhesive patch comprises of cotton fibers (p 19, claim 43).

It would have been obvious to one having ordinary skill in the art to impregnate or add antibacterial compositions comprising a pharmaceutical carrier in patches and cotton patches because of the prior art teachings. The prior art Buseman et al. teaches

adhesive patches in treating bacterial infections in mammals by topical application. The prior art teaches the backing of the patch comprises cotton fibers. One having ordinary skill in the art at the time of the invention would have been motivated to make patches comprising 1, 5 pentane diol and use it in a method of inhibiting the growth of multiple-resistant bacteria because Swanbeck teaches the antimicrobial properties of the compound and Buseman teaches that antimicrobial compositions can be provided via adhesive patches in treating bacterial infections in mammals.

Response to Arguments

(1) 112(1) rejection:

Applicants state in the response that "the multiple-resistant bacteria has been specified as at least one of the bacterial referenced on page 1, line 34 to page 2, line 2, and in Example 1. Accordingly, it is respectfully submitted the rejection under 35 USC §112, first paragraph is moot and can be withdrawn".

In response, as stated above in the rejection, despite the advanced studies in antibiotic resistance of bacteria it is still not predictable from the art or from the specification that 1, 5 pentane diol can inhibit the growth of all strains of enterobacteriaceae with plasmid-encoded extended- spectrum beta lactamases and antibiotic-resistant Serratia maltophilia or coagulation-negative Staph with respect to antibiotics other than fucidic acid as claimed known so far and yet to be discovered. Applicants have shown inhibitory effect of pentane 1, 5 diol for MR resistant against fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim for the bacterial strains tested. Huff (Naturalnews.com, Mar 6 2010) reported that a new

drug resistant bug, Acinetobacter (superbug) is plaguing many hospitals. Also, Baker (Naturalnews.com, July 18 2009) reported about CA-MRSA type of drug resistant bug causing pneumonia. Even the Applicants in their arguments (9/29/2010, p1) have stated that "The art is replete with antibiotics which have failed to provide an inhibitive effect with respect to multiple-resistant bacteria". Applicants have claimed that pentane,1, 5 diol is multiple resistant bacteriostatic agent, an agent that will inhibit the growth of existing multiple drug resistant strains as well the ones to be discovered. It is not predictable from the results provided by the Applicant that all strains of Serratia maltophilia which is resistant to several antibiotics will be inhibited by administration of 15% of pentane 1,5 diol. The instant claims encompass administration of 15% of pentane 1,5 diol as multiple resistant bacteria bacteriostatic agent, the guidance of the specification is towards determining the MIC and growth inhibition for multiple resistant bacteria where the drugs are fucidin, methicillin, vancomycin (only for enterococcus), ciprofloxacin and timetoprim. One having ordinary skill in the art have to conduct experiments to find out whether pentane 1,5 diol is multiple resistant bacterial bacteriostatic agent for different multiple drug resistant bacteria, such as enterobacteriaceae with plasmid-encoded extended- spectrum beta lactamases and antibiotic-resistant Serratia maltophilia or coagulation-negative Staph with respect to antibiotics other than fucidic acid as claimed and for their various strains for the drugs that they are resistant to. First a person of ordinary skill in the art have to conduct experiments or research from prior art to find out the type of drug(s) the bacterial strain is resistant to and then conduct experiments with 1, 5 pentane diol to find out at whether

the compound inhibits the growth of that particular strain and its minimum inhibitory concentration. Therefore, it would require undue, unpredictable experimentation to find whether pentane 1,5 diol is a multiple-resistant bacteriostatic agent, that is an agent that inhibits the growth of all multiple resistant bacteria that is known and yet to be discovered.

(2) 103(a) rejection:

(1) Swanbeck et al. (U.S. 5,369,129): Applicants' argue that there is no reasonable expectation that the same agent would be effective against a multiple-resistant strain and quite to the contrary, the fact that the bacteria have developed resistance to agents used to combat it suggests looking elsewhere for a solution to the multiple resistant problem. Moreover, the mechanism by which most multi-resistant bacteria operate is largely unknown. Given the fact that there is no reasonable expectation of success, it is respectfully submitted that this rejection is untenable. In response, nothing in the swanbeck patent or elsewhere states that the bacteria have become resistant to 1, 5 pentane diol agent. In fact it would have been obvious to a person of ordinary skill in the art to try using 1, 5 pentane diol agent in inhibiting the growth of the bacteria that has become resistance to other drugs when the prior art teaches the effect of 1, 5 pentane diol in inhibiting the growth of certain bacteria such as S.aureus, S.epidermidis, C.albicans, T.rubrum, P.avale.

Applicants state in the arguments that "To the extent that some antibiotics have shown at least some degree of effect on multiple-resistant bacteria, they do not include any member of the broad class of diols. The activity of clindamycin, noted by the

Examiner, is therefore not relevant". In response, Clindamycin example was given to show that it would have been obvious to a person of ordinary skill in the art that a multiple resistant bacteria can be inhibited using antibiotics like clindamycin and it would have been obvious to a person of ordinary skill in the art at the invention to have tried 1, 5 pentane diol agent in inhibiting the growth of the bacteria that has become resistance to other drugs when the prior art teaches the effect of 1, 5 pentane diol in inhibiting the growth of certain bacteria such as S.aureus, S.epidermidis, C.albicans, T.rubrum, P.avale. It would have been obvious to one having ordinary skill in the art to try using pentane 1,5 diol in treating multiple resistance bacteria for cost-effective reasons and availability.

(2) Goodman et al: Applicants' argue that Goodman is deficient in that it fails to teach or suggest that any alkylene glycol has multiple-resistant antibiotic activity, and therefore fails to teach glycol use as an active agent. In response, Goodman teaches compositions comprising alkylene glycol including pentylene glycol and hence using the composition comprising the same compound will have the same property even Goodman has not stated that pentylene glycol has multiple-resistant antibiotic activity. The prior art swanbeck has shown that 1,5 pentane diol has inhibitory effect against various types of bacteria. Any properties exhibited by or benefits provided by the composition are inherent and a chemical composition and its properties are inseparable.

(3) Tsao: Applicants' argue that Tsao also fails to teach or suggest that 1,5-pentanediol will have any multiple-resistant antibiotic activity. As stated above 'Any properties exhibited by or benefits provided by the composition are inherent and a

chemical composition and its properties are inseparable'. Tsao has been cited for its teaching of the amount of certain alkylene glycols, including 1,5-propylene glycol and Noll has been cited to teach the addition of detergents in antimicrobial compositions.

Conclusion

No claims are allowed.

Applicants' amendments necessitated the modified rejections presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Umamaheswari Ramachandran whose telephone number is 571-272-9926. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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